Opening Statement
The Honorable Joe Barton
Chairman
Subcommittee on Oversight and Investigations
Committee on Commerce
U.S. House of Representatives
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Today, the Subcommittee continues its inquiry into the impact on consumers from the policies and practices of the Food and Drug Administration (FDA) and the adequacy of the Food, Drug and Cosmetic Act.

The Subcommittee will be hearing from FDA officials about its newly announced final policy on home collection testing systems for drugs of abuse. We did not receive the policy until last night. In a small concession to common sense, the FDA will allow some urine-based home collection testing systems for drugs of abuse to be sold to parents without a doctor's prescription. This is a partial reversal of FDA's position at our last FDA oversight hearing where the Agency maintained that the marketing to parents of urine cups and hair envelopes for drug testing purposes required a premarket application. By this requirement, the FDA insisted that such common items needed to be regulated as sternly as pacemakers or heart valves that are implanted in the human body. That position was based on FDA's concerns about such societal and ethical factors as "family discord" in assessing parents' ability to handle the results of a drug test.

When we looked at this question in detail last September, we were promised swift correction of this unjustifiable intrusion into an area of American life that most members of Congress never in their wildest imagination would have considered the purview of the FDA. FDA issued an interim policy within a few days of the hearing which allowed some urine-based home drug-testing kits to be marketed over-the-counter without an application until FDA came up with a **final** policy. The Vice President of the United States, in the election debate with Jack Kemp, even claimed that retraction of this policy as an example of the Clinton Administration's commitment to curbing senseless regulation. **Almost** four months went by without the FDA issuing a final policy. Only after we announced our intentions to hold this hearing and after FDA's first approval of a premarket application for a home **drug**-testing system to be available without a doctor's prescription, did FDA finally **finish** its work on the final policy.

I have reviewed FDA's final policy. Although FDA has eased its regulation of urine-based drug testing systems, it now threatens to block over-the-counter access of hair testing systems for drugs of abuse for parents and employers, who may consider hair testing easier and less intrusive. The FDA, under its final policy, in a convoluted way has determined that hair testing is good enough for law enforcement and the courts but not parents and employers. The FDA has in fact rewarded itself with a legal victory it could not win against a hair testing company that took them to court to challenge FDA's decision that a hair envelope is a Class III medical device. It now attempts to grab jurisdiction on its own over

hair testing for drugs of abuse. Notwithstanding the effectiveness of these tests established by 10 years of research funded by the Veterans Administration, the U.S. Navy, the National Institute of Justice, and the American Society for Industrial Security, and the documentation in several hundered scientific publications in the world, under FDA's policy, hair testing drug kits must be considered Class III devices until FDA approves a laboratory diagnostic test using hair, assuming such an application is made. In the process, FDA may well have weakened law enforcement by providing criminal defendants with a new defense in the courtrooms of using non-approval by FDA to block the admissibility of positive drug tests using hair. In addition, the FDA has not relented on using societal and ethical factors in its product reviews.

Finally, the FDA continues to assert its thin jurisdictional claim over such things as urine cups. It is truly a tribute to how out of control this agency has become when it claims that their medical device jurisdiction covers seemingly nonmedical devices such as: television remote controls, weight lifting equipment, automobile and foot driving controls, wheelchair elevators, portable telephones, sunglasses, shoe deodorizers, and powered toothbrushes.

I am fed up and I believe that I speak for a majority of my colleagues in this regard. If the FDA and its lawyers cannot be trusted to curb their excessive grab for power, then the statute will have to be altered to limit their authority and funds will have to removed from their discretion. I authored the medical device provision of FDA reform in the last Congress. If the FDA continues to insist that a urine cup, a bag full of silicone, mailing envelopes, and the like are medical devices, we may well be forced to clarify the limits of their power in this Congress. Congressman Bob Barr, who represents Sunny Cloud and helped generate the Subcommittee's investigation of FDA's regulation of drug testing, and I are prepared to introduce legislation to instill a common sense definition of "medical devices". With sensible boundaries, the FDA can focus on the true public health issues of medical devices.

We look forward to hearing from witnesses for the FDA. Today, we will continue to attempt to address the concerns that have been raised so that FDA management or reform legislation can correct any problems that are identified.